

DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)	Course Number:
	Module: 3
	Page 1 of 52
INSTRUCTOR NOTES	TRAINING MATERIALS AND SUGGESTIONS
ISO 9001	Slide #3-1
20 QUALITY SYSTEM ELEMENTS Show the slide to the students - probably not necessary to read the list. Point out that each will be discussed to a limited degree.	Slide #3-2
OBTAINING COPIES OF ISO STANDARDS Give these addresses to the students if they are interested. <u>American Society for Quality (ASQ)</u> 611 E. Wisconsin Ave., PO Box 3005 Milwaukee, WI 53210 Tel: 414-272-8575 or 800-248-1946 <u>American National Standards Institute (ANSI)</u> 11 W. 42nd St. New York, NY 10036 Tel: 212-642-4900, Fax: 212-302-1286	Slide #3-3
ISO 9001: NSI/ASQ Q9001 This slide begins the element-by-element study of the 20 quality system requirements of ISO 9001. Point out again that ISO 9001 and ANSI/ASQC Q9001 are identical in the requirements. As you go through the 20 elements, some should get more attention than others. Where no notes are given, you should touch on that element very lightly.	Slide #3-4
DESCRIPTION AND DISCUSSION OF 20 Q9001 QUALITY SYSTEM ELEMENTS	Slide #3-5

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 2 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION</p> <p>4.1 Management Responsibility</p> <p>Element 4.1 of ISO 9001 defines those parts of a quality system that only management has the authority to implement.</p> <p><u>Intent</u></p> <p>In order to assure that an enterprise's quality objectives and commitment to quality and customer satisfaction are consistently understood, implemented, and maintained at all levels, the standard requires management's active involvement to accomplish the following:</p> <ul style="list-style-type: none"> • Establish quality policy • Define quality responsibility, authority, and interrelationships • Provide adequate resources for quality management system implementation • Continuously review the effectiveness of the quality management system <p><u>Benefit</u></p> <p>Focusing management attention on the development and communication of quality policy, the assignment of specific quality responsibility and authority, and the planning and deployment of resources assures that the organization's quality and customer satisfaction objectives are widely understood and implemented.</p> <p>Management's regular review of quality system performance assures that all levels of the organization continue to place an appropriate priority on quality improvement and customer satisfaction.</p>	<p>Slide #3-6</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 3 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <p><u>Interpretation</u></p> <p>The ISO 9001 standard recognizes that only management has the authority and responsibility to implement several critical elements of the enterprise's quality management system:</p> <ul style="list-style-type: none"> • Executive management must establish a documented quality policy that will accomplish the following: <ul style="list-style-type: none"> – Define management's quality objectives – Define management's commitment to quality – Be relevant to the expectations and needs of the organization's customers – Address the organization's goals • The documented quality policy must be widely communicated so that all levels of the organization understand its intent and routinely implement it. • To minimize organizational gaps and overlaps and to establish accountability, management must define and document the responsibility, authority, and relationship of all personnel who manage, perform, or verify work that affects quality. <p>This is particularly important in order to preserve the freedom and authority of those personnel who must verify conformance; identify, correct, and prevent product and process problems; and control the use of non-conforming product.</p> <ul style="list-style-type: none"> • After establishing its quality policy and the organizational responsibility and authority for work affecting quality, the enterprise's management must accomplish the following: <ul style="list-style-type: none"> – Determine the type and level of personnel and other resources necessary to adequately implement that policy and responsibility – Make those resources available – including the assignment of adequately trained personnel <p>The enterprise's quality planning process (ISO 9001 element 4.2.3.b) is where these personnel, skill, and material resource requirements could be identified and developed.</p>	<p>Slide #3-6 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 4 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <ul style="list-style-type: none"> • The standard requires an organization's executive management to appoint a "management representative." This person must be a member of the enterprise's management team and may have other duties in addition to those related to the quality system. <ul style="list-style-type: none"> – They must have clearly defined responsibility and authority for ensuring that an ISO 9000-compliant quality system is developed, documented, implemented, maintained, and improved. – They will also be responsible for reporting quality system performance to executive management for its review, with the objective of improving the quality system and quality performance. <p>This delegated responsibility from executive management may also include liaison with customer, regulatory, or third-party registrars who conduct assessments of the enterprise's quality management system.</p> <p>In very small enterprises, there may be no need to appoint a management representative if executive management performs those functions.</p> <ul style="list-style-type: none"> • Executive management must periodically review the performance of its quality system: <ul style="list-style-type: none"> – The review frequency must be defined and must be sufficiently frequent to assure the continuing effectiveness of the quality management system. – These reviews must assess the suitability and effectiveness of the quality system for the following purposes: <ul style="list-style-type: none"> • To satisfy the requirements of the organization's previously documented quality policy and objectives • To satisfy the requirements of ISO 9001 – Data that could form the basis of these quality system reviews might include the following: <ul style="list-style-type: none"> • Current and overdue corrective action requests arising from the following: <ul style="list-style-type: none"> – Customer complaints – Internal audit findings 	<p>Slide #3-6 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 5 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <ul style="list-style-type: none"> - Customer or third-party audit findings - Findings from audits of supplier quality systems - Supplier product deficiencies • Field service and field failure data • Trends in non-conformance prevention, detection, and correction costs • Status of process improvement teams and other preventive action projects • Process performance metrics, such as first pass yield, cycle time, and coefficient of process capability • Written records of quality management system reviews must be generated and maintained in accordance with the standard's Quality Records provisions (ISO 9001, element 4.16). <p>Such records might include meeting minutes showing the responsibility and completion schedule for action items resulting from the review.</p>	<p>Slide #3-6 (concluded)</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION</p> <p>4.2 Quality System</p> <p>Element 4.2 of ISO 9001 addresses the overall quality system structure and content needed to deploy executive management's quality policy and management's delegated authority and responsibility for work affecting quality.</p> <p><u>Intent</u></p> <p>A quality system that defines and documents how key processes are intended to function is the first step toward reducing process variability and increasing product consistency and conformance to customer and internal requirements.</p> <p><u>Benefit</u></p> <p>A documented quality system improves process and product consistency and reduces the extra labor, material, and time needed to correct non-conformities. Cost and schedule performance will improve and will also become more</p>	<p>Slide #3-7</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 6 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED) consistent and predictable. Customers will receive fewer errors and defects and will be more satisfied, so post-delivery complaint costs will also decline. <u>Interpretation</u> The standard requires each enterprise to develop, implement, and maintain a documented quality management system, whose objective is consistent product conformance to specified requirements. The enterprise's quality system is defined in the following:</p> <ul style="list-style-type: none"> • Its quality manual • Written procedures that define the enterprise's operating processes • Quality planning that defines how the specified requirements for particular products, projects, or contracts will be addressed <p><u>Quality Manual/Operating Procedures</u></p> <ul style="list-style-type: none"> • The organization's quality system must be defined in a quality manual. • The quality manual must define the types, levels, and interrelationships of the documentation that defines the organization's quality system. A "tree" diagram showing how various types of policies, plans, procedures, and work instructions relate to one another could be used. • The quality manual must either include, or identify by reference, the specific documented operating procedures that define the organization's quality system. • The quality manual and the associated operating procedures must address the elements of the ISO 9001 standard and must be consistent with the enterprise's documented quality policy and objectives. • The operating procedures may be more or less detailed, based on the complexity of the processes being described and the level of experience and training of the associated personnel. Where required to assure consistent understanding and implementation of key processes, the operating procedures may reference consistent detailed work instructions that need not be part of the quality manual. 	<p>Slide #3-7 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 7 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <ul style="list-style-type: none"> • Sometimes a flow chart, or even a well designed form, may adequately define the who, what, when, and how of a process. In this case, the flow chart or form might be referenced in an extremely brief operating procedure. Because such flow charts and forms are effectively the management-approved definition of the intended process, they should be numbered and revision controlled. • Once the enterprise has addressed all elements of ISO 9001 in its quality manual and documented procedures, the responsibilities, processes, and requirements defined in those documents must be effectively implemented. <p><u>Quality Planning</u></p> <ul style="list-style-type: none"> • For each product, project, or contract, the enterprise must define and document how it plans to address the applicable requirements. • Whether products are developed in response to accepted orders, or are developed in advance of customer demand, the quality planning process should interface with the related process for review of proposal and order requirements addressed in ISO 9001 element 4.3 — Contract Review. • The quality planning process should also interface with the design development process addressed in ISO 9001 element 4.4 — Design Control. Ideally, quality planning and design development are concurrent and interactive. Quality Function Deployment (QFD) is a useful tool to allow all affected groups to simultaneously identify, correlate, and balance key customer requirements, design features, and process control elements. • Because some enterprises may have fully integrated requirements review, design development, and quality planning processes, the standard provides great flexibility regarding how quality planning must occur and be documented. The standard requires a documented quality planning activity, but does not require the creation of discrete quality plans, per se. The standard only requires that the enterprise consider the need for preparation of discrete quality plans. 	<p>Slide #3-7 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 8 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <p>Regardless of how the organization conducts its quality planning effort, the following items must be considered:</p> <ul style="list-style-type: none"> - Identification of necessary resources, including the need for development or acquisition of the following: <ul style="list-style-type: none"> • New or improved process or process control technology • New or modified equipment, tools, or facilities to produce, inspect, test, install, or service the product • Additional personnel resources or upgraded skills - Identification of any needed measurement capability that may exceed current state of the art so that adequate capability can be developed in a timely fashion - Identification of new or revised written procedures or work instructions to support the design, creation, process control, inspection, test, installation, or servicing of the anticipated product - Identification of appropriate verification points in the design, development, procurement, production, installation, and servicing processes and definition of the required types of verification at each point - Definition of objective or subjective acceptance standards for all requirements - Identification of the type, frequency, and point of generation of all necessary quality records • At its simplest, a quality plan might only need to identify by reference which elements of the enterprise's quality manual, written procedures, and work instructions will apply to the specific product, project, or contract in question. 	<p>Slide #3-7 (concluded)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 9 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <p>4.3 Contract Review</p> <p>Element 4.3 of ISO 9001 specifies the necessary elements in an enterprise's process for establishing/reviewing requirements in outgoing proposals and incoming orders.</p> <p><u>Intent</u></p> <p>When undertaking new projects, contracts, or product-development activities, a systematic requirements development and review process will result in requirements that are comprehensive, clearly understood, adequately documented, and fully communicated to all affected groups at the earliest stage of activity.</p> <p><u>Benefit</u></p> <p>Unanticipated requirements result in unplanned costs, adverse schedule impacts, requests for concessions, and customer dissatisfaction. The later these unexpected requirements appear, the larger the adverse impacts. These unforeseen requirements are much less likely when the needs of all concerned groups are solicited in a structured manner, fully documented and communicated, and understood and reconciled as early in the product development cycle as possible.</p> <p><u>Interpretation</u></p> <p>The standard requires each enterprise to establish and maintain documented procedures defining their requirements review process:</p> <ul style="list-style-type: none"> • The process must assure that all applicable requirements are clearly defined, documented, and communicated: <ul style="list-style-type: none"> – Prior to submission of a proposal – Before order acceptance <p>Such requirements might include product performance, safety, reliability, statutory, regulatory, and other internal and customer requirements.</p>	<p>Slide #3-8</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 10 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONCLUDED)</p> <ul style="list-style-type: none"> • The process must define how any unwritten requirements that are received will be reviewed before acceptance. • The review process must provide for the following: <ul style="list-style-type: none"> – Identification and resolution of differences between the requirements in the proposal and those in the subsequent order – Identification and resolution of unclear or conflicting requirements – Resolution of any disparity between requirements and the organization's capability to meet those requirements • Menu-style requirements checklists are one way to assure that the requirements of customers and all affected groups are consistently identified and documented • How the output from the contract review process will affect the quality planning process (ISO 9001, element 4.2.3) and the design and development planning process (ISO 9001, element 4.4.2) could also be defined. • A written record of requirements reviews must be generated and maintained in accordance with the standard's Quality Records provisions (ISO 9001, element 4.16). Such records might include the following: <ul style="list-style-type: none"> – The requirements checklists discussed above. – Requirements review meeting minutes showing action items to resolve unclear, conflicting, or unachievable requirements <p>The above requirements checklists could also serve as the following:</p> <ul style="list-style-type: none"> • The basis for subsequent design review agendas where design outputs must be verified as conforming to all design input requirements • The record of those design review meetings — in accordance with ISO 9001, elements 4.4.6 and 4.16 • The process for reviewing, communicating, and implementing modifications to the requirements in proposals or orders must also be documented 	<p>Slide #3-8 (concluded)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 11 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <p>4.4 Design Control</p> <p>Element 4.4 of ISO 9001 defines the major elements that each enterprise's design and development process must address.</p> <p><u>Intent</u></p> <p>Systematically designing and documenting the process for design, clearly defining all organizational interfaces, and actively planning the development of each new product design will assure that the organization consistently meets all customer and internal requirements.</p> <p><u>Benefit</u></p> <p>Designs that do not fully meet internal and regulatory requirements and user needs require unplanned design modifications that result in adverse cost and schedule impacts and customer dissatisfaction. Design modifications will have a tolerable impact if made before substantial design effort begins. Impact will be much greater if changes are made to completed designs, and the cost and customer impact can be extreme for design changes made after product has been created, delivered, or deployed.</p> <p>However, the frequency and magnitude of such problems can be substantially reduced in the following circumstances:</p> <ul style="list-style-type: none"> • All necessary steps in the design and development process are clearly defined and documented. • The requirements of all stakeholders and the design-related responsibilities of all affected groups are systematically defined and planned before significant design effort begins. • Design outputs are reviewed by all affected groups and verified as meeting their design input requirements. • Completed designs are operationally validated as meeting user needs. • Design changes are systematically managed. <p><u>Interpretation</u></p> <p>The standard requires each enterprise to establish and maintain documented operating procedures defining how the design of their products and services will be developed, controlled, and verified as meeting requirements:</p>	<p>Slide #3-9</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 12 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <ul style="list-style-type: none"> • For each design and development project, documented plans must define the necessary design activities and the associated responsibility for their implementation. The design and development plan must be reviewed and updated as required during the evolution of the design. • The organizational and technical interfaces between all groups concerned with the design and development effort must be defined. Concerned groups that are often outside the design group include Reliability Engineering, Quality Engineering System Safety Engineering, Maintainability Engineering, Producibility Engineering, and Regulatory Compliance. Design and development planning, quality planning (ISO 9001 element 4.2.3), and the review of proposal and order requirements (ISO 9001 element 4.3) can be concurrent and interactive. Tools like Quality Function Deployment (QFD) might be used to identify, correlate, and balance key customer requirements, design features, and necessary control elements in design, production, and verification processes. These interfaces could be documented in the required design and development plan discussed above. • Design activities must be carried out by qualified personnel, equipped with adequate materials, facilities, and support. • The methods and responsibilities for identifying design requirements must be defined. These requirements might include customer requirements, reliability, maintainability and operational safety requirements, performance requirements, producibility and inspectability requirements, and statutory or regulatory requirements. • The above design inputs must be documented and reviewed for adequacy and completeness. For any conflicting, unclear, or incomplete design requirements, the group that originally imposed the requirements must be involved in their resolution. Menu-style checklists are one way to identify, document, review, and record the resolution of each group's design requirements. 	<p>Slide #3-9 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 13 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <ul style="list-style-type: none"> • The product design that is the output of the design and development process must accomplish the following: <ul style="list-style-type: none"> – Be documented. Typical design documentation might include product drawings, specifications, software, and operating and servicing instructions. – Satisfy the design input requirements. – Include design call-outs that address the safe and proper functioning of the product. These might include the definition of applicable operating instructions, handling, packaging and storage specifications, and installation, maintenance, and disposal requirements. – Define the acceptance criteria for each design characteristic, either by inclusion in the design documentation or by reference. – Be expressed in terms that can be verified as meeting design input requirements. For instance, a design call-out for "surface cleaning per X-999 process specification" is a verifiable way to implement a difficult to verify design input requirement like "free of surface contaminants." – Be expressed in terms that can be validated as meeting user needs. For example, a user expectation that there be "no sharp edges" is impossible to confirm unless specified as "break all edges to .XX minimum radius." • Documents that define the completed design must be reviewed before release. • At appropriate stages of the design and development process, the design must be verified as conforming to design input requirements during formal design reviews: <ul style="list-style-type: none"> – Design review meetings must include representatives from all groups concerned with the design stage being reviewed. – The definition of when design reviews will be conducted and what other design verification methods are to be used must be documented in the design and development plan discussed above. 	<p>Slide #3-9 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 14 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONCLUDED)</p> <p>In addition to design reviews, verification of conformance to design input requirements might include tests, inspections, demonstrations, independent engineering analyses and calculations, and comparison of design elements to similar elements of proven designs.</p> <ul style="list-style-type: none"> - Suitable records of all design reviews and records of any other design verification activities must be made and maintained in accordance with the Quality Records provisions of ISO 9001, element 4.16. <p>Design review records might include meeting minutes showing design review action items. Log books and computer files of engineering analyses, and completed test reports would be typical examples of other verification records.</p> <ul style="list-style-type: none"> • Designs must also be validated as meeting user needs: <ul style="list-style-type: none"> - Validation is typically performed under defined operating conditions. - Validation usually follows the successful verification that the design meets all previously defined design input requirements. - Validation is usually performed on the completed product, but may also be performed at intermediate design stages or on important sub-systems. - Multiple validations may be needed to confirm that the design meets user needs in each anticipated application or environment. • Design changes must be documented, reviewed, and approved by authorized personnel before implementation. <p>In schedule-critical circumstances, quick-change processes with less formal documentation and fewer reviews may be appropriate. However, such abbreviated change processes must be documented and individual design changes still must be documented and authorized before implementation.</p>	<p>Slide #3-9 (concluded)</p>

DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)	Course Number:
	Module: 3
	Page 15 of 52
INSTRUCTOR NOTES	TRAINING MATERIALS AND SUGGESTIONS
Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION <u>Design Control System Graphic</u>	Slide #3-10
Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION 4.5 Document and Data Control <p>Element 4.5 of ISO 9001 defines the requirements for controlling documents and data associated with the operation of the enterprise's quality management system.</p> <p><u>Intent</u></p> <p>Systematic management of the creation, release, distribution, and modification of documents that affect quality will assure that the contents are adequate and that the correct revisions of all necessary documents are available at every location where they are needed to correctly perform the work.</p> <p><u>Benefit</u></p> <p>Fewer errors and omission and their adverse impacts to cost and schedule will occur when only fully adequate and authorized documents and revisions are used by all personnel whose work affects quality.</p> <p><u>Interpretation</u></p> <p>ISO 9001 requires each enterprise to establish and maintain written procedures defining their process for controlling all documents and data used in work affecting quality:</p> <ul style="list-style-type: none"> • Documents and data that are required for the operation of the enterprise's quality system must be controlled. These controlled documents could be in any form, such as hard copy, electronic media, or microfiche, and should include the following: <ul style="list-style-type: none"> – The organization's quality policy and quality manual – Procedures (e.g., Drawing Release, Supplier Qualification, Design Verification) – Inspection and test plans, procedures, and instructions 	Slide #3-11

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 16 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <ul style="list-style-type: none"> - Work instructions and key business forms - Process descriptions and flow charts - Audit plans, design development plans and project quality plans - Internal, customer and supplier product drawings - Internal, National, International, and customer specifications or standards - Installation, operation, and servicing manuals - Reports and other records whose use affects current operations - Process/product evaluation or control software - Customer deliverable documents - The master document control list that defines the release and revision status of all other controlled documents <p>Other customer and supplier documents and data might also require control to the extent that their use affects the quality of the enterprise's products and services</p> <ul style="list-style-type: none"> • Before release for use, controlled documents must be reviewed for completeness and adequacy, and approved by authorized personnel. • Revised documents must be reviewed by the same functions that approved the originals unless alternate review and approval requirements are clearly defined: <ul style="list-style-type: none"> - Reviewers must have access to any related information that supports the document's revision and that may be helpful in their review. - To the extent practical, the nature of the revisions should be identified in the document or its attachments. • All necessary documents must be made available at each location where work affecting quality is performed. Availability in the general area of grouped workstations may be adequate to support operations. Delivery of hard copy or on-line availability via computer networks are both acceptable. 	<p>Slide #3-11 (continued)</p>

DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)	Course Number:
	Module: 3
	Page 17 of 52
INSTRUCTOR NOTES	TRAINING MATERIALS AND SUGGESTIONS
Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONCLUDED) <ul style="list-style-type: none"> To preclude the unintended use of un-released drafts or obsolete documents, a master document control list showing each document's currently authorized revision level must be continually updated and maintained and must be made readily available to document users. Obsolete documents must be promptly removed from all points of use. Suitable methods could include physically retrieving obsolete hard copy or posting replacement documents to computer networks with a notification of availability to network users. Any obsolete documents that are retained for legal or knowledge preservation purposes must be clearly identified. Use of a red "OBSOLETE" ink stamp on each document is one way to satisfy this requirement. 	Slide #3-11 (concluded)
Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION Document Control System Stress the point that poor documentation and document control continue to be the number one reason for non-certification.	Slide #3-12
Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION 4.6 Purchasing Element 4.6 of ISO 9001 defines the quality-related requirements for each enterprise's procurement processes. <u>Intent</u> Using supplier selection criteria that include the adequacy of their quality management system and their past performance will maximize the probability of the supplier meeting the purchaser's requirements. Systematically establishing procurement requirements that are comprehensive and clear will assure that suppliers better understand all purchaser expectations.	Slide #3-13

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 18 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <p><u>Benefit</u></p> <p>When suppliers are selected based on tangible evidence of their ability to meet customer requirements, the frequency of supplier deficiencies and the resulting unplanned costs and adverse schedule impacts will be greatly reduced.</p> <p>If purchase requirements are solicited in a systematic way and are clearly documented and communicated to the supplier, omissions, misunderstandings, and the costs and schedule delays of return and replacement will be minimized.</p> <p><u>Interpretation</u></p> <p>The ISO 9001 standard requires that each enterprise establish and maintain documented procedures defining their processes for selecting suppliers and specifying purchase requirements:</p> <ol style="list-style-type: none"> Suppliers must be evaluated and selected based on their ability to meet the enterprise's procurement requirements. Quality related evaluations might include the following: <ul style="list-style-type: none"> Review of the supplier's Quality Manual using ISO 9001 and this guide. On-site assessment of the supplier's operational compliance with their own Quality Manual and documented operating procedures. Audit checklists based on ISO 9001 and this guide could be used to evaluate the adequacy of the supplier's quality management system. <p>The purchaser could perform these quality system audits, or review the audit reports of other enterprises that use the same supplier, or accept the supplier's ISO 9000 registration by an accredited third-party assessor.</p> <ul style="list-style-type: none"> On-site assessment of the capability of the supplier's facilities, processes, equipment, and personnel to meet applicable technical standards and product requirements. 	<p>Slide #3-13 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 19 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <ul style="list-style-type: none"> • Review of the supplier's performance record on previous, similar orders. Such records could include the receiving inspection results for prior deliveries, reports of previous supplier audits, surveys of purchase requester satisfaction, records showing adequate and timely closure of requested corrective actions, and reports of problems encountered in the field. <p>2. Based on evaluations, such as the above, the enterprise must maintain records of acceptable suppliers. For convenience, such records could list all approved suppliers by commodity type and might also rank suppliers based on defined criteria. This ranking could be used as the basis for prescribing more or less control on future orders (see paragraph 3 below).</p> <p>3. The extent of the controls to be applied to each procurement must be defined. These controls could include activities required of the supplier and activities performed internally. Such controls might include the following:</p> <ul style="list-style-type: none"> • Purchaser's approval of quality-critical supplier procedures, process equipment, process parameters, or personnel certifications • Purchaser's approval of supplier's product qualification plan and/or qualification results • Liaison personnel assigned to the supplier's facility during critical activities • Periodic surveillance audits of the supplier's quality system and quality-critical processes • Release of supplier's production activity following approval of the first article produced • Sampling or 100% source inspection • Sampling or 100% receiving inspection • Review of supplier submitted inspection and test data or process control charts • Oversight testing, performed by the purchaser or by a third-party lab 	<p>Slide #3-13 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 20 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <p>The type and extent of control must be based on the type of product or service being acquired, the impact of the procured items on final product or service quality, the supplier's performance record, and the assessed effectiveness of the supplier's quality management system.</p> <ul style="list-style-type: none"> • Those purchaser-imposed controls that will directly affect the supplier's operations must be defined in the procurement documentation that will be sent to the supplier (see paragraph 3 above). • Procurement documents must clearly describe the product or service being ordered including name, type, grade, model number, etc. For specifications, drawings, standards, inspection or test instructions, and other applicable documents, the title, number, revision, date, or other identifiers must be defined in procurement documents. • The number, title, and revision of any quality management system standard to be implemented by the supplier must be defined. • If the enterprise plans to verify an order's conformance at its supplier's facility, specific methods for verification and subsequent release for delivery must be defined in procurement documents. If the enterprise's customer reserves the right to verify the conformance of sub-contracted product at the facility of the enterprise's supplier, such arrangements must also be defined in procurement documents. • Before transmittal to the supplier, the enterprise must review and approve its purchasing documentation to assure that the specified requirements are appropriate, adequate, and complete. <p>A menu-style checklist could be used to assure that appropriate procurement requirements are consistently selected, documented, and reviewed. The checklist could also communicate those requirements to the enterprise's purchasing function and to the supplier as an attachment to the purchase order. The checklist might also become the receiving function's inspection plan for order acceptance and serve as the archival record of conformance.</p>	<p>Slide #3-13 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 21 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONCLUDED)</p> <ul style="list-style-type: none"> • The enterprise's customer might, by contract, reserve the right to verify conformance of subcontracted work before its delivery. Such verification could occur at the enterprise's facility or at the facility of the enterprise's supplier. The verification could be done by customer personnel or by their duly appointed representatives. Despite such pre-delivery customer verification: <ul style="list-style-type: none"> – The enterprise must not treat their customer's successful product verification as evidence of adequate control of quality by the enterprise's supplier. – The ISO 9001 standard requires the enterprise to be ultimately responsible for the product's conformance to requirements, including any subsequent rejection by the enterprise's customer. 	<p>Slide #3-13 (concluded)</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION</p> <p>4.7 Control of Customer-supplied Product</p> <p>Element 4.7 of ISO 9001 defines the requirements for the management of customer furnished articles.</p> <p><u>Intent</u></p> <p>The systematic management of customer-supplied property will assure that such articles are functional and available for use at the necessary time.</p> <p><u>Benefit</u></p> <p>When the receipt, verification, storage, maintenance, and use of customer-supplied articles is effectively controlled, deterioration and loss will be minimized. The extra costs, delays, and customer dissatisfaction caused by repair or replacement of such property will be substantially reduced.</p> <p><u>Interpretation</u></p> <p>Each organization must establish and maintain documented procedures defining how customer-supplied property will be controlled, including the following elements:</p>	<p>Slide #3-14</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 22 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <ul style="list-style-type: none"> • Customer furnished articles must be verified as conforming to requirements at the time of receipt. Review of customer provided records and performance of tests or inspections could be undertaken. • Despite such verification of conformance by an enterprise, the ISO 9001 standard requires the customer to be ultimately responsible for the acceptability of the product they are providing. • The enterprise must assure that customer supplied articles are appropriately identified, stored and maintained in order to preclude loss, damage or deterioration. • Customer property that is lost, damaged or found unsuitable for use must be recorded, in accordance with ISO 9001 element 4.16, and promptly reported to the customer. <p>4.8 Product Identification and Traceability</p> <p>Element 4.8 of ISO 9001 defines the requirements for product identification and for unit or batch traceability.</p> <p><u>Intent</u></p> <p>Systematic identification of products with their part or model number significantly reduces the probability of mix-ups and inappropriate use.</p> <p>Additionally, identifying individual units or batches with serial numbers or lot numbers facilitates failure analysis for root cause, permits separation of suspect product from other product of the same part or model number, and permits targeted customer notification or recall.</p> <p><u>Benefit</u></p> <p>Clear identification of products makes efficient stocking and issuance practices possible. It also substantially reduces inadvertent use of similar but incorrect items and the schedule, cost, and customer satisfaction impacts of correcting such errors.</p>	<p>Slide #3-14 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 23 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONCLUDED)</p> <p>Unit or lot traceability permits the cost-effective identification, recall, and replacement of only those specific units or batches that may be identified as non-conforming or failure prone. Without such traceability, the cost of repair or replacement of all inventory may unduly influence the decision to use marginal product.</p> <p>Batches or units with a traceable processing history make material and process related failure analysis possible. Systematic process improvement is also easier when the cause and effect relationship between process and product can be identified.</p> <p><u>Interpretation</u></p> <p>The standard requires each enterprise to determine whether documented procedures for identification and traceability of product are appropriate for their situation:</p> <ul style="list-style-type: none"> • When appropriate, the organization must identify products by suitable means during receipt, processing, delivery, installation, and servicing: <ul style="list-style-type: none"> – Drawing numbers or the manufacturer's part or model number are frequently used. Sometimes they are expressed as universal product (bar) codes. – Suitable identification methods might include indelible ink stamping, tagging, adhesive labels, chemical etching, or mechanical engraving. – Product identification contained only in accompanying documents, such as process travelers or packing slips, might be acceptable if usage and storage environments reduce the risk of commingling the documentation between similar products. • When specified by customers or regulatory requirements, or due to internal needs, each enterprise will establish, maintain, and record the unique batch or unit identity of products: <ul style="list-style-type: none"> – Serial numbers and lot numbers are typically used. – Operations logs, work station bar code readers, processing travelers, or other suitable records could be used to make the product's location or processing history traceable. 	<p>Slide #3-14 (concluded)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 24 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION</p> <p>4.9 Process Control</p> <p>Element 4.9 of ISO 9001 defines the requirements for the control of production, installation, and servicing processes that affect quality.</p> <p><u>Intent</u></p> <p>The systematic planning and active management of processes that affect quality will reduce unintended process variability, which will result in products and services that more consistently satisfy requirements.</p> <p><u>Benefit</u></p> <p>When process variability is systematically controlled, products and services will more frequently meet requirements. Scrap, unbudgeted rework, and associated schedule delays will be reduced, as will unplanned overtime and premium transportation to minimize such delays.</p> <p>Controlled processes produce higher levels of first-time conformance to requirements, so less inspection and fewer audit hours may also be justifiable. With fewer errors and defects, fewer will slip through inspection and create customer dissatisfaction.</p> <p><u>Interpretation</u></p> <p>The standard requires each enterprise to accomplish the following:</p> <ul style="list-style-type: none"> • Identify and plan those processes that directly affect the quality of their products and services. These might include production, inspection, installation, and servicing processes. Such processes must be conducted under controlled conditions, including the following: <ul style="list-style-type: none"> – Only suitable equipment, facilities, and operating environments must be used. Ideally, process performance has been quantified and found to be capable of consistently meeting all requirements when operated in a controlled manner. Graphical process capability studies can be performed to verify that the process is inherently capable of meeting requirements. 	<p>Slide #3-15</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 25 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <p>Some truly state-of-the-art processes may not be capable of consistently meeting all requirements, even when operated in a fully controlled manner. However, as the best available, these processes may still be considered suitable.</p> <p>Processes that are inherently capable of meeting requirements often fail to do so because of inadequate frequency and types of controls; intuitive, rather than statistically sound process monitoring and adjustment; and physical deterioration due to inadequate maintenance.</p> <ul style="list-style-type: none"> - When appropriate, process equipment and operating parameters should be approved by authorized personnel before release for use. Completion of the process capability study discussed above could serve as the basis for authorization of process start-up. - The intended manner of process operation must be documented. Written procedures, work instructions, or flow charts may be used to define the "who, what, how, and when" for each process step. The process description might also reference the forms, equipment, visual standards, measurement devices, process parameters, and any other documents required to implement the process. - Personnel must be familiar, and comply with, the documented procedures, standards and plans: <ul style="list-style-type: none"> • Any necessary training in the requirements of applicable procedures could be defined in the process documentation or in the enterprise's related training procedure (ISO 9001, element 4.18). - The responsibility for use of the controlled procedures, standards, and plans that define process operation could be specified in the process documentation or as specified in the enterprise's Quality System Requirements procedures (ISO 9001, element 4.1.2.1). 	<p>Slide #3-15 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 26 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <ul style="list-style-type: none"> - Compliance with documented procedures could be monitored by the enterprise's internal audit program in accordance with ISO 9001, element 4.17. Regularly scheduled internal audits will uncover the need for revised procedures or for additional training so that practices match procedures. • Appropriate process parameters and product characteristics must be monitored and controlled: <ul style="list-style-type: none"> - The parameters and characteristics to be monitored could be identified in documented process procedures and work instructions. These procedures and work instructions might include documentation, video tapes, or representative product samples. <ul style="list-style-type: none"> • Gauges and instruments that are used for monitoring process parameters and product characteristics must be controlled in accordance with ISO 9001, element 4.11. • Simple histograms and run charts, or more sophisticated statistical process control charts, could be used to record process and product data for use in adjusting process operation. These statistical techniques must be used in accordance with ISO 9001, element 4.20. - Clear workmanship standards for product acceptability and process operation must be defined, documented, and implemented. These standards could include written descriptions, photos or illustrations, and physical samples. 	<p>Slide #3-15 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 27 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONCLUDED)</p> <ul style="list-style-type: none"> - Suitable process maintenance must be provided to preserve or improve the original process capability. This might include preventive maintenance for gauges and instruments used in production and inspection processes. Documented maintenance plans and schedules as well as maintenance completion logs or tags could be used. • For special processes, where examination of the product to verify conformance to requirements is impractical, the process must be carried out using one or both of the following control techniques: <ul style="list-style-type: none"> - The process must be carried out using pre-qualified equipment, process parameters, and personnel whose capability to consistently meet specified process and product requirements has been evaluated. Records of the results of such equipment, process parameter, and personnel qualifications must be maintained. These records must be managed in accordance with ISO 9001, element 4.16. - The process must be continuously monitored and controlled. To be considered "continuous," process monitoring and control should be performed with sufficient frequency to detect and correct unintended process changes before non-conforming product is created. 	<p>Slide #3-15 (concluded)</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION</p> <p>4.10 Inspection and Testing</p> <p>Element 4.10 of ISO 9001 defines the requirements for conducting inspections and tests to verify that specified product requirements have been met.</p> <p><u>Intent</u></p> <p>Systematically planning appropriate inspections and tests and performing them in a controlled manner will assure that products and services, once accepted, do in fact meet specified requirements.</p>	<p>Slide #3-16</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 28 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <p><u>Benefit</u> Poorly planned and conducted tests and inspections can result in costly delays and customer dissatisfaction if non-conforming product goes undetected. Adequately planned and controlled inspections and tests will minimize this problem.</p> <p>Adequately documented test and inspection results provide enterprises and their customers with permanent evidence that products and services meet all specified requirements and will be suitable for use.</p> <p><u>Interpretation</u> To accurately assess whether or not specified requirements have been met, each enterprise must establish and maintain documented procedures defining which inspections and tests are to be conducted, how they are to be conducted, and what records must be generated:</p> <ul style="list-style-type: none"> • For each product, project, or contract, the Quality Plan (ISO 9001, element 4.2.3) may be used to identify which inspections and tests are required and what records are to be created. Otherwise, this information must be contained in the applicable documented inspection and test procedures. • Incoming products must be verified as conforming to specified requirements before they are released for use. Requirements checklists could be completed as part of the purchase request process and transmitted to the supplier and the receiving function. When properly formatted, the requirements checklist can serve as the receiving inspection plan and the required quality record for that procurement. • The extent and nature of receiving inspections must be based on the type of product and its intended application, the degree of control exercised by the purchaser and supplier at the supplier's facility, and the availability of supplier-furnished process control charts, test results, and inspection results. <p>The extent of receiving inspection called for could also be tied to the supplier's performance history as reflected in the supplier's ranking in the enterprise's list of approved suppliers (ISO 9001, element 4.6.2).</p>	<p>Slide #3-16 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 29 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <ul style="list-style-type: none"> • In-process tests and inspections must also be conducted in accordance with planned and documented procedures. These tests and inspections might include random product "audits" by roving inspectors, product measurement or Go/No Go checks made by process operators, set-up or first-article inspection, and automated inspection stations between specified processing steps. • Incoming and in-process products that are released for urgent use before verification of conformance is complete must be positively identified (e.g., ink stamping, tagging). A record of their incomplete verification must also be made to facilitate subsequent recall and completion of all prescribed inspections and tests. Such records of premature release must be treated as Quality Records in accordance with ISO 9001, element 4.16. These records might include annotated inspection logs and annotated processing travelers. • Final inspections and tests must be conducted in accordance with planned and documented procedures. Finished product must not be released until the following are accomplished: <ul style="list-style-type: none"> – All specified processing has been completed. – All required incoming, in-process, and final inspections and tests have been completed and conformance to specified requirements has been verified. – All required data or documentation must also be available and must be approved by authorized personnel before final product release. A standardized checklist could be used to assure consistent final release practices. • All products that have been verified as not conforming to specified requirements must be treated in accordance with ISO 9001, element 4.13 — Control of Non-conforming Product. 	<p>Slide #3-16 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	Course Number:
	Module: 3
	Page 30 of 52
INSTRUCTOR NOTES	TRAINING MATERIALS AND SUGGESTIONS
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <ul style="list-style-type: none"> For incoming, in-process, and final inspections and tests, records must be maintained. These records must accomplish the following: <ul style="list-style-type: none"> Provide evidence of inspection and test completion Document the resulting pass/fail status relative to defined acceptance criteria Identify the authorized individual or function that accepted or released the product based on the inspection or test results Be treated as Quality Records in accordance with ISO 9001, element 4.16 <p>Properly designed inspection logs, process travelers, and test or inspection reports might be used to satisfy this records requirement.</p>	Slide #3-16 (concluded)
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION</p> <p>4.11 Control of Inspection, Measuring and Test Equipment</p> <p>Element 4.11 of ISO 9001 defines the requirements each enterprise must address for the selection, control, calibration, and maintenance of inspection, measurement, and test equipment.</p> <p><u>Intent</u></p> <p>Actively managing the selection, calibration, use, and maintenance of inspection, measuring, and test equipment will assure that measurement uncertainty is known and is consistent with the measurement capability required for effective process control and product verification.</p> <p><u>Benefit</u></p> <p>Quantifying, minimizing, and controlling measurement uncertainty will substantially reduce the risk of accepting non-conforming product or inadvertently rejecting good product.</p> <p><u>Interpretation</u></p> <p>The ISO 9001 standard defines the requirements that must be addressed when using inspection, measuring, and test equipment:</p>	Slide #3-17

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 31 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION</p> <ul style="list-style-type: none"> Each enterprise must establish and maintain documented procedures defining their processes for selection, control, calibration, and maintenance of all inspection, measuring, and test equipment (including test software) that is used to demonstrate conformance of products to specified requirements. Detailed work instructions for specific calibration and maintenance activities may also be needed. <p>The selection, control, calibration, and maintenance of other inspection, measuring, and test equipment that may affect quality, but is not used to demonstrate product conformance, need not be governed by documented procedures. However, they must be selected, controlled, calibrated, and maintained in accordance with all other requirements of ISO 9001, element 4.11.</p> <p>Measurement equipment not used for product verification might include gauges and instruments used for product development testing, set-up, or maintenance of process equipment and monitoring of process parameters.</p> <ul style="list-style-type: none"> The measurements to be made during design, development, production, installation, or servicing must be identified. Such measurements would include those necessary to effectively monitor and control processes and to verify product conformance to requirements. <p>Identification of these measurements could be accomplished as part of the quality planning process (ISO 9001, element 4.2.3) that leads to the development of test and inspection procedures.</p> <ul style="list-style-type: none"> The required accuracy and precision for each measurement identified above must be defined. Only inspection, measuring, and test equipment that is fully capable of meeting those accuracy and precision requirements must be selected for use. Standardized data sheets can be used to perform accuracy and precision studies to confirm that measurement capability matches requirements. 	<p>Slide #3-17 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 32 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <ul style="list-style-type: none"> • Specific inspection, measurement, and test equipment, whose use can affect product quality, must be identified. This could be accomplished using a data base referenced in documented procedures or quality planning. These gauges and instruments must be calibrated and adjusted at prescribed intervals or prior to use, as appropriate: <ul style="list-style-type: none"> – Calibration standards that are certified as traceable to the National Institute of Standards and Technology must be used. – Where NIST-traceable standards do not exist, the means of calibration must be documented. This could be done in the Quality Plan (ISO 9000, element 4.2.3) for the applicable product, project, or contract. • Inspection, measuring, and test equipment that cannot be calibrated, but is used to verify product conformance, must be shown to be capable of verifying product acceptability: <ul style="list-style-type: none"> – Capability must be demonstrated before release for use and must be re-checked at prescribed intervals. – The type and frequency of such capability checks must be defined. – Records of these capability checks must be maintained in accordance with ISO 9001, element 4.16. <p>Typical articles that cannot be calibrated might include photographs or product samples that are used as workmanship standards, or the software needed to operate test or inspection equipment or analyze measurement input and convert it to an output display.</p> • The calibration process must be defined; the documented procedure contained in or referenced in the enterprise's Quality Manual could be used. The calibration process must include the following elements: 	<p>Slide #3-17 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 33 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <ul style="list-style-type: none"> - The specific identity and location of each piece of inspection, measurement, and test equipment that requires calibration must be defined. The data base described above could be used. - The prescribed calibration frequency and method of calibration must be defined. The same data base might be used. - The limits within which gauges and instruments may be adjusted, without being declared out of calibration, must be defined. When the above limits are exceeded, the validity of previous inspection and test results must be assessed and documented. One method would be to document, review, and disposition the affected product in the same manner as non-conforming product (ISO 9001, element 4.13). - Records of calibrations must be maintained in accordance with ISO 9001, element 4.16. - The calibration status of individual pieces of inspection, measurement, and test equipment must be identified: <ul style="list-style-type: none"> • The calibration due date could be displayed on a label affixed to the inspection, measurement, and test device. • Gauges or instruments that are not being calibrated because their use does not affect quality could display a "Not Calibrated" label so that inappropriate use is minimized. • Environmental conditions must be provided that are suitable for both the calibration and use of inspection, measurement, and test equipment. Temperature, humidity, and cleanliness may all require varying levels of control in the areas where both calibration and instrument usage occur, in order to ensure measurement accuracy and precision. • The accuracy, precision, and resulting fitness for use of inspection, measurement, and test equipment must be protected from inadvertent deterioration by implementing appropriate controls on handling, preservation, and storage. 	<p>Slide #3-17 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 34 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONCLUDED)</p> <ul style="list-style-type: none"> • These methods could be defined in the enterprise's documented procedure for control of inspection, measurement, and test equipment or in their handling, storage, and packaging procedure. • The means of preventing unauthorized adjustments to inspection, measurement, and test equipment must be defined. Comparative standards used for product acceptance and test software must also be protected. Limited access inspection rooms, cabinets, and tool cases or tamper-evident seals could be used. • If required by the customer, technical data pertaining to the functional adequacy of the enterprise's gauges and instruments must be made available. Such data might include capability studies of measurement precision and accuracy, gauge calibration reports, and certifications of calibration standards. 	<p>Slide #3-17 (concluded)</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION</p> <p>4.12 Inspection and Test Status</p> <p>Element 4.12 of ISO 9001 defines the requirements an enterprise must address to adequately identify each product's inspection and test acceptance or rejection status.</p> <p><u>Intent</u></p> <p>To preclude the inadvertent use of product that has not successfully completed all prescribed processing and verification steps, each item's inspection and test status should be readily identifiable.</p> <p><u>Benefit</u></p> <p>The avoidable delays, extra costs, and customer dissatisfaction resulting from inappropriate release of product for processing, assembly, or use will be minimized when product acceptance status is clearly identified.</p> <p><u>Interpretation</u></p> <p>The standard requires each enterprise to define how inspection and test status will be identified in its quality plan or in documented procedures:</p>	<p>Slide #3-18</p>

DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)	Course Number:
	Module: 3
	Page 35 of 52
INSTRUCTOR NOTES	TRAINING MATERIALS AND SUGGESTIONS
Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONCLUDED) <ul style="list-style-type: none"> • The status of product conformance or non-conformance to specified inspection and test requirements must be identified. It should be readily evident whether or not specific units or batches have completed the necessary inspections and tests. Once an inspection or test is completed, it should also be evident whether the product has passed or failed. Tags, stamps, labels, and processing travelers could be used. • The identification of inspection and test acceptance status must be maintained during all phases of production, installation, and servicing. • Only product that has successfully passed all specified inspections and tests or has been authorized for use in accordance with documented procedures for control of non-conforming product (ISO 9001, element 4.13) can be released for use. 	Slide #3-18 (concluded)
Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION 4.13 Control of Non-Conforming Product <p>Element 4.13 of ISO 9001 defines the requirements each enterprise must address to adequately control non-conforming products.</p> <p><u>Intent</u></p> <p>The systematic management of non-conforming product should prevent its unintended use.</p> <p><u>Benefit</u></p> <p>To minimize the budget impact and customer dissatisfaction from products that fail to meet requirements, it is essential that known non-conforming product be controlled to preclude its inadvertent use.</p> <p>The systematic documentation and evaluation of non-conforming product also provides a basis for improvement of supplier and internal processes.</p>	Slide #3-19

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 36 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <p><u>Interpretation</u></p> <p>The standard requires each enterprise to establish and maintain documented procedures that preclude the unintended use of non-conforming product:</p> <ul style="list-style-type: none"> • Non-conforming product includes such items as raw materials, procured articles, and parts, components, or assemblies that do not meet specified requirements. Product that fails to function as intended is typically treated as non-conforming. • Non-conforming product must be identified. Reject tags, stamps, labels, or other suitable means can be used. • Non-conforming product must be documented. Non-conformance reports are often used to fully identify the product and its condition and to facilitate and record the evaluation and disposition of the product. • To the maximum extent practical, physical segregation of non-conforming product from acceptable product is required. Limited access storage rooms, locked cabinets, or roped off areas for large articles could be used. • The individual or group that is authorized to evaluate and disposition the non-conforming product for use, rework, repair, scrap, or replacement must be defined. This function is sometimes delegated to a Material Review Board comprised of members who can knowledgeably address product design margins and functionality, safety, and necessary supplier or internal corrective actions. • Non-conforming product must be evaluated in accordance with documented procedures. Such procedures might include the following: <ul style="list-style-type: none"> – Define when customer involvement is required – Provide guidelines for authorizing repair, regrading, or use-as-is dispositions – Define when failure analysis must be undertaken – Identify when the design rationale for a disposition must be documented 	<p>Slide #3-19 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 37 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <ul style="list-style-type: none"> • The identified non-conformance and the resulting evaluation and disposition must be communicated to all concerned functions. This might be accomplished by distribution of the Non-conformance Report. Concerned functions might include those responsible for product design or for process design, maintenance, and operation; the purchasing function or supplier quality function; the enterprise's supplier or customer; or perhaps regulatory agencies. • If required, the customer or its representative must approve the proposed use of non-conforming product or its repair to a functional but still non-conforming condition: <ul style="list-style-type: none"> – A record of such customer concessions must be kept, clearly describing the condition that was accepted and describing the nature of any repairs. – These records must be managed in accordance with ISO 9001, element 4.16. • Non-conforming product that has been reworked to a conforming condition or has been repaired to a functional, but still nonconforming condition must be re-inspected in accordance with documented procedures. These documented procedures might include standard inspection instructions or special inspection and acceptance requirements defined by an authorized Material Review Board. • The management and closure of corrective actions resulting from evaluation of non-conforming product could be addressed in the documented procedure for control of non-conforming product or in the related corrective action procedures required by ISO 9001, element 4.14. 	<p>Slide #3-19 (concluded)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 38 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION</p> <p>4.14 Corrective and Preventive Action</p> <p>Element 4.14 of ISO 9001 specifies the major elements that must be present in each enterprise's processes for corrective action and for preventive action.</p> <p><u>Intent</u></p> <p>Corrective action processes strive to eliminate the root causes of existing product and service non-conformities. Preventive action processes seek to identify possible non-conformities before they occur and eliminate their root causes.</p> <p><u>Benefit</u></p> <p>Actively managed corrective and preventive action processes will systematically improve process performance, resulting in fewer product and service problems that affect customers and require unbudgeted resources to evaluate and correct.</p> <p>A sustained effort to prevent non-conformities from occurring will improve first time conformance and justify reduced inspection and audit expenditures for non-conformance detection.</p> <p><u>Interpretation</u></p> <p>The standard requires each enterprise to establish and maintain documented procedures for implementing both corrective and preventive action processes:</p> <ul style="list-style-type: none"> • Any operating changes resulting from the corrective and preventive action processes must be fully implemented, and the applicable documented procedures must be revised. Corrective and preventive action processes that permanently capture upgraded methods are the basis for long-term continuous improvement. • The extent of the preventive or corrective actions taken to eliminate future or current non-conformities should be appropriate for the magnitude of the problem and the resulting risk. 	<p>Slide #3-20 (continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 39 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <ul style="list-style-type: none"> Information on preventive and corrective actions must be provided to management for inclusion in their regular review of the effective functioning of the enterprise's quality system (ISO 9001, element 4.1.3). The documented procedure for corrective action must include the following: <ul style="list-style-type: none"> An effective process for handling customer complaints and reports of product non-conformance. The analysis of product, process, and quality system non-conformities to identify and document their causes: <ul style="list-style-type: none"> Such non-conformities might include the following: <ul style="list-style-type: none"> Findings from internal audits, customer, or third-party audits, audits by regulatory bodies, and the enterprise's audits of their supplier's quality systems Action items from executive management's reviews of quality system effectiveness Rejections from source, receiving, in-process, and final inspections and tests Current customer complaints and field failures Analytical techniques like "fish bone" cause and effect charts could be used to identify both the immediate causes of non-conformance and their root causes. The results of the cause and effect investigation must be recorded in accordance with the quality records provisions of ISO 9001, element 4.16. A simple Corrective Action Request (CAR) form could be used. The corrective actions needed to permanently eliminate the identified root causes must be determined. The above mentioned CAR could be used to document the specific actions necessary to eliminate the identified root causes. Verification must be provided that the specified corrective action has been taken and that it has actually eliminated subsequent non-conformance. The period required to confirm no further recurrence should be significantly longer than the average frequency of past occurrences. Closure data could be recorded on the Corrective Action Request form. 	<p>Slide #3-20 (continued)</p>

DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)	Course Number:
	Module: 3
	Page 40 of 52
INSTRUCTOR NOTES	TRAINING MATERIALS AND SUGGESTIONS
Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONCLUDED) The documented procedure for preventive action must include the following: <ul style="list-style-type: none"> • The analysis of appropriate operating data to detect emerging trends and assignable causes that may result in future nonconformities. Such data sources could include the following: <ul style="list-style-type: none"> – Equipment operation logs and process control charts – Records of requirements reviews and design reviews – Records of design changes – Supplier performance records – Process cycle time and process capability metrics – Process yield metrics and defect rankings – Internal and external audit reports – Customer-granted concessions – Service records and field failure records Cost of quality data might also be reviewed in order to optimize the level of defect prevention effort versus conformance assessment effort and defect correction effort (see Section 2.21 of this guide) <ul style="list-style-type: none"> • Determination of the actions needed to deal with potential problem areas that warrant preventive action • The implementation of the appropriate preventive action and the verification that the preventive action has been effective in eliminating the problem area. One measure of effectiveness might come from monitoring the data that highlighted the original problem for a significantly longer period than the previous frequency of occurrence 	Slide #3-20 (concluded)
Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION Element 4.14 Graphic	Slide #3-21

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 41 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION</p> <p>4.15 Handling, Storage, Packaging, Preservation, and Delivery</p> <p>Element 4.15 of ISO 9001 specifies the requirements that each enterprise's processes for product handling, storage, packaging, preservation, and delivery must meet.</p> <p><u>Intent</u></p> <p>Clearly defined requirements and processes for handling, storage, packaging, preservation, and delivery will significantly reduce inadvertent damage, deterioration, or unavailability of necessary articles at all stages of processing.</p> <p><u>Benefit</u></p> <p>Product that is damaged or is allowed to deteriorate during receipt, processing, storage, or delivery will cause unpredictable extra costs, schedule slippage, and customer dissatisfaction that could be avoided by designing and implementing systematic product integrity controls.</p> <p><u>Interpretation</u></p> <p>The standard requires each enterprise to establish and maintain documented procedures for handling, storage, packaging, preservation, and delivery:</p> <ul style="list-style-type: none"> • Handling methods that prevent product degradation must be developed and implemented: <ul style="list-style-type: none"> – Controls should be implemented throughout the enterprise's operations, from receiving until responsibility for the product passes to another party. – Training, such as electrostatic discharge prevention or clean room practices, could be provided. – The design of workstations, fixtures, tools, gauges, containers, and handling equipment can be optimized to significantly reduce handling damage. • Designated storage areas must be used to prevent damage or deterioration pending in-process use or delivery. Methods for authorizing receipt to and removal from such stock areas must be defined: 	<p>Slide #3-22</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 42 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION</p> <ul style="list-style-type: none"> - Secure cabinets, rooms, or fenced cribs could be used. - For just-in-time or pull production systems, specifically designated fixtures, carousels, racks, dollies, or bins might be used. - Stocking and withdrawal controls might include the following: <ul style="list-style-type: none"> • Receiving Inspection's "release for stocking" stamp • Withdrawal from raw stock only with build travelers issued by Production Control • In-process stocking or withdrawal based on authorized signatures on process travelers indicating completion of necessary operations • Removal from finished stores only with the certification group's shipment release stamp • To detect possible deterioration, regular assessments of stored product must be made: <ul style="list-style-type: none"> - Shelf life date stamps or tags can be employed for limited life items. - Regularly scheduled full or cycle inventories can be performed to assess product integrity at the same time that the accuracy of inventory quantity and identity is assessed. - First-in-first-out stocking systems could be used to minimize the potential for product deterioration. • Use of packaging, packing, and marking processes and materials must be specified and controlled: <ul style="list-style-type: none"> - For procured articles, authorized marking and packaging materials could be specified in product drawings or referenced packaging specifications. - The internal application of approved marking, packaging and packing materials, methods, and containers could be defined in standard packing procedures, processing travelers, or authorized checklists of selectable packaging requirements. 	<p>Slide #3-22 (continued)</p>

DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)	Course Number:
	Module: 3
	Page 43 of 52
INSTRUCTOR NOTES	TRAINING MATERIALS AND SUGGESTIONS
Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONCLUDED) <ul style="list-style-type: none"> To preserve integrity and avoid unintended commingling while product is in the enterprise's control, appropriate methods, materials, and environments must be specified and implemented. When contractually specified, the enterprise's responsibility could extend through delivery, installation, and commissioning. Data sheets, travelers, work instructions, and installation and service manuals could be used to define and communicate intended practices. 	Slide #3-22 (concluded)
Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION 4.16 Control of Quality Records Element 4.16 of the ISO 9001 standard defines the requirements for management of quality records. <u>Intent</u> Quality records are the basis for the acceptance of product and for the measurement and improvement of operating processes and the quality management system. <u>Benefit</u> Quality records are a major source of data needed to efficiently plan, budget, and manage functional organizations and to analyze and improve the effectiveness of their processes and the enterprise's quality system. Quality records also provide management, suppliers, and customers with tangible evidence of conformance to their requirements.	Slide #3-23

DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)	Course Number:
	Module: 3
	Page 44 of 52
INSTRUCTOR NOTES	TRAINING MATERIALS AND SUGGESTIONS
Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION <u>Interpretation</u> <p>The standard requires each enterprise to establish and maintain documented procedures for the identification, collection, indexing, access, filing, storage, maintenance and eventual disposal of quality records.</p> <p>Quality records are those documents or data that provide evidence of the following:</p> <ul style="list-style-type: none"> • The effective operation of the organization's quality management system • The capability of key personnel, processes, or suppliers • The controlled operation of processes that affect quality • Product conformance to specified requirements <p>Such quality records might include the following:</p> <ul style="list-style-type: none"> • Design review meeting minutes • Corrective action requests • Training records • Management review meeting minutes • Calibration reports • Prevention, detection and correction costs • Customer complaints • Design verification calculation • Design validation test results • Records of customer-supplied product • Inspection and test reports • Internal audit reports • Completed processing travelers • Completed certification examinations • Supplier audit results • Control charts from special processes • Supplier performance data • Requirements review meeting minutes • Product non-conformance reports • Approved customer concessions 	Slide #3-23 (continued)

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 45 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <p>Data provided by suppliers for purchased articles that affect the quality of final products may also need to be managed as quality records.</p> <p>The standard's specific requirements include the following:</p> <ul style="list-style-type: none"> • All quality records must be legible. • Records must be stored and retained so as to be readily retrievable. Records would probably be considered readily retrievable if they could be accessed in time to avoid a disruption to operations. Using another approach, retrieval within 24 hours is often used as a rule of thumb. • The storage environment for quality records must preclude loss, damage, or deterioration. Hardcopy, microfilm, and electronic records may have differing needs for temperature, humidity, and contamination control and fire or electromagnetic field protection. • The minimum retention period and the method and authority for eventual disposal of the records must be defined and documented. When required by the customer, quality records must be available for customer evaluation for an agreed period. When not contractually defined, retention periods are often based on regulatory requirements, liability, or product lifetime considerations. Retention periods of 5 to 7 years are frequently encountered. 	<p>Slide #3-23 (continued)</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION</p> <p>4.17 Internal Quality Audits</p> <p>Element 4.17 of ISO 9001 defines the requirements for each enterprise's internal quality audit process.</p> <p><u>Intent</u></p> <p>Internal quality audits provide organizations with a continuous review of the effectiveness of their quality management system. Internal quality audits also characterize the level of day-to-day compliance to the enterprise's approved process and product requirements.</p>	<p>Slide #3-24</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 46 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <p><u>Benefit</u></p> <p>Opportunities for the continuous improvement of operating processes will be systematically identified through regularly scheduled internal audits of the enterprise's quality management system.</p> <p>Internal audits also help to identify areas of degraded practices or obsolete procedures that can result in costly product non-conformities and customer dissatisfaction.</p> <p><u>Interpretation</u></p> <p>The standard requires each enterprise to establish and maintain documented procedures for planning and implementing internal quality audits:</p> <ul style="list-style-type: none"> • Internal audits must verify the effective operation of the quality system and whether quality-related activities and associated results comply with specified requirements. For each operational area, audit checklists could be developed based on ISO 9001, this guide, and the organization's documented quality plans and operating procedures. • Audits should be scheduled based on the status and importance of the activity being assessed. Areas with recurring process, product, or procedure problems warrant more frequent and more comprehensive audits than low-risk or problem-free areas where less frequent audits of a few key elements may be sufficient. • The selected auditors must not have a direct responsibility for the operations being audited. For example, Human Resources personnel might be precluded from participating in audits of the training process, but they could effectively audit in the area of management responsibility (ISO 9001, element 4.1). • Results of internal quality audits must be as follows: <ul style="list-style-type: none"> – Recorded and the records managed in accordance with the requirements of ISO 9001, element 4.16 	<p>Slide #3-24 continued)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 47 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONTINUED)</p> <ul style="list-style-type: none"> – Coordinated with personnel responsible for the areas being audited. Since internal audits are improvement oriented, area personnel could accomplish the following: <ul style="list-style-type: none"> • Assist auditors in their development of audit checklists • Provide on-scene assistance to the auditor in scheduling personnel availability, explaining operating methods, and obtaining relevant documents and records • Provide real-time validation or correction of the auditor's observations • Assist the auditor in analyzing problem areas for root cause and in defining appropriate corrective actions. <p>When the exit interview occurs, there would already be complete understanding by all parties.</p> <ul style="list-style-type: none"> • Results of internal quality audits should also be part of executive management's review of the effectiveness of the quality management system, in accordance with ISO 9001, element 4.1.3. • Management personnel responsible for the area being assessed must take timely and effective action to correct any identified deficiencies. <p>Providing trend charts on the age of open corrective action requests for executive management's review (ISO 9001, element 4.1.3) could provide the necessary visibility to assure that resources are prioritized for timely process improvement.</p> <ul style="list-style-type: none"> • Follow-up audits must be conducted to verify and document that corrective actions have been implemented and that they have been effective in eliminating the original problem. These records of follow-up audits must be managed in accordance with ISO 9001, element 4.16. 	<p>Slide #3-24 (concluded)</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION</p> <p>Internal Audit System Graphic</p>	<p>Slide # 3-25</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 48 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION</p> <p>4.18 Training</p> <p>Element 4.18 of ISO 9001 defines the requirements for managing the identification and delivery of necessary training.</p> <p><u>Intent</u></p> <p>Systematically identifying, planning, and providing appropriate training to personnel whose work affects quality will ensure that they possess the necessary knowledge, skills, and proficiency to consistently meet requirements.</p> <p><u>Benefit</u></p> <p>The unbudgeted time and effort needed to correct errors and omissions will be reduced when personnel are systematically provided with the training necessary to become fully proficient in their job. Fewer errors and omissions will also result in increased customer satisfaction, particularly in service-oriented processes where personnel have frequent customer contact.</p> <p><u>Interpretation</u></p> <p>The standard requires each enterprise to establish and maintain documented procedures for managing the identification and delivery of quality-critical training:</p> <ul style="list-style-type: none"> • The training needs of all personnel whose work affects quality must be defined. This might include executive management, supervision, professional, and hourly personnel. Some training may be specified by regulatory bodies or be defined in contracts. However, most training will probably be internally driven, based on the enterprise's need to satisfy customer expectations for high quality, timely delivery, and low cost. • Personnel must be qualified for their specific assigned tasks by having or receiving the required training, education, and experience: 	<p>Slide #3-26</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 49 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONCLUDED)</p> <ul style="list-style-type: none"> – Training data sheets could be developed, defining the required knowledge base and proficiency level for each job classification. In-house or external training sources could then be identified for each type of required training. <ul style="list-style-type: none"> • The need for special skills for each product, project, or contract could first be identified in the enterprise's quality planning documents (ISO 9001, element 4.2.3), and entered in the appropriate training data sheets. • The need for certification of personnel who operate special processes (ISO 9001 element 4.9), including the need for proficiency testing, could first be identified in the enterprise's quality planning documents (ISO 9001, element 4.2.3) and entered in the appropriate training data sheets. • Each employee's unique experience and skills could be recorded on the appropriate data sheet for their job classification. With a well designed data sheet, any gaps between actual and required skills would be automatically highlighted. • Each organization must systematically plan, budget, and ensure the delivery of the necessary training. Completion of the training data sheet suggested above would identify specific training needs and could also act as the work sheet for costing and scheduling the training, thus becoming that individual's training plan. • Records of personnel training must be maintained in accordance with ISO 9000, element 4.16. Recording the completion of training on the above mentioned data sheet could produce a comprehensive record of the entire training identification, planning, budgeting, and delivery cycle. 	<p>Slide #3-26 (concluded)</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 50 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION</p> <p>4.19 Servicing</p> <p>Element 4.19 of ISO 9001 defines the requirements for managing servicing activities.</p> <p><u>Intent</u></p> <p>Defining, documenting, and actively managing servicing processes should result in optimum product performance that meets customer expectations.</p> <p><u>Benefit</u></p> <p>The systematic design and delivery of product servicing will maximize the probability that servicing requirements will be met and that product quality will not be inadvertently degraded by servicing errors or omissions.</p> <p>Preventing servicing errors and omissions will reduce unexpected cost and schedule impacts to the enterprise and their customers. The loss of product use by the customer will also be minimized.</p> <p><u>Interpretation</u></p> <p>Where product servicing is a specified requirement, the standard requires each enterprise to establish and maintain documented procedures for their servicing processes. Product servicing might occur during or after delivery, installation, or commissioning. Such documented servicing procedures should define the following:</p> <ul style="list-style-type: none"> • How the product servicing is to be performed. The intended servicing methods, tools, equipment, materials and product operating parameters could be documented. • How conformance to requirements will be verified. Any necessary inspection and testing methods, gauges, instruments, equipment, and acceptance criteria could be defined. • How the completion of servicing and its conformance to specified requirements will be reported. Checklists or work orders completed by the service person and countersigned by the user might be used. 	<p>Slide #3-27</p>

<p align="center">DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)</p>	<p>Course Number:</p>
	<p>Module: 3</p>
	<p>Page 51 of 52</p>
<p align="center">INSTRUCTOR NOTES</p>	<p align="center">TRAINING MATERIALS AND SUGGESTIONS</p>
<p>Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION</p> <p>4.20 Statistical Techniques</p> <p>Element 4.20 of ISO 9001 defines the requirements for identification and application of appropriate statistical techniques to the enterprise's processes and products.</p> <p><u>Intent</u></p> <p>When properly applied, statistical techniques are powerful tools for the analysis, management, and improvement of product designs and operating processes.</p> <p><u>Benefit</u></p> <p>Simple graphical tools, commercially available software, and advanced mathematical techniques help characterize and improve process performance leading to more frequent conformance to the enterprise's requirements and reduced operating costs.</p> <p>Statistical techniques are used to analyze and improve the safety and reliability of product designs. They can also be used as preventive action tools to evaluate operating records and identify emerging trends.</p> <p>Statistical sampling plans reduce the leadtime and resources required to verify product conformance to specified requirements.</p> <p><u>Interpretation</u></p> <p>The standard requires each enterprise to identify necessary applications for statistical techniques and establish and maintain documented procedures for their use:</p>	<p>Slide #3-28</p>

DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 3: ISO 9000 QUALITY SYSTEM ELEMENTS (ISO 9001)	Course Number:
	Module: 3
	Page 52 of 52
INSTRUCTOR NOTES	TRAINING MATERIALS AND SUGGESTIONS
Q9001 20 ELEMENTS: DESCRIPTION AND DISCUSSION (CONCLUDED) <ul style="list-style-type: none"> • Work processes must be evaluated to identify beneficial uses for specific statistical techniques. Statistical techniques might be used as follows: <ul style="list-style-type: none"> – Evaluate and improve the reliability of new product designs – Analyze, improve, and control the unintended variability of key processes – Predict or analyze field failures – Conduct valid customer surveys using cost effective sampling – Predict product performance based on limited prototype testing – Uncover cause and effect relationships – Analyze supplier performance and highlight adverse trends – Release new processes and products for production based on limited qualification data – Analyze customer complaint data – Perform lot sampling to verify product conformance to requirements – Characterize the accuracy and precision of gauges and instruments – Analyze operating data to uncover emerging trends and initiate preventive actions before significant problems arise <p>The areas identified for application of statistical techniques could be defined in the Quality Plan for each product, project, or contract (ISO 9001, element 4.2.3).</p> <ul style="list-style-type: none"> • The means of deploying and controlling the identified statistical techniques must be documented. Requirements for applying statistical techniques could be defined in applicable operating procedures or work instructions. 	Slide # 3-28 (concluded)